DETAILED ACTION

This action is responsive to communication filed 6/29/2010.

Claims 4, 6-10 and 43-62 are under current examination.

To allow the entry of the new rejection(s) below, this action is made non-final.

Drawings

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. See Figures which provides sequences without any sequence identifiers.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-10 and 43-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are directed to a "non-naturally occurring mutant polypeptide"; see claim 4 as a representative. It is not clear whether the interpretation of this claim is a mutant polypeptide mutated by the hand-of-man which may include those mutants found in nature or a mutant peptide that is specifically *not* found in nature. Note that the instant

specification fails to provide a definition for a "non-naturally occurring mutant polypeptide". For reasons of this action, the claim is interpreted as a mutant peptide that is specifically *not* found in nature.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6-10 and 43-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to (in part) a purified or non-naturally occurring mutant polypeptide comprising an amino acid that is 95 (see instant claim 48), 96 (claim 4), 97 (claim 43), 98 (claim 44), 99 (claim 45) or 99.5 % (claim 50) identical to the retroviral envelope amino acid sequence set forth by SEQ ID NO: 2. Note that the claims are further drawn to multiple specific functional limitations, including the homologous polypeptide to be capable of mediating retroviral infection of either a mouse or human cell and capable of mediating a higher infectivity in human cells than MCF-247 virus; see at least instant claims 4, 9, 10, etc.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
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> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a known or disclosed non-functional characteristic (structure) that correlates to the function.

All of the claims are drawn to (in part) a "non-naturally occurring mutant polypeptide" based on the sequence set forth by SEQ ID NO: 2 and a "non-naturally occurring mutant polypeptide" is interpreted as any mutant polypeptide that is not found in nature; see discussion above. The instant specification fails to disclose all of those mutants that is *or* is not found in nature within the 639 amino acid sequence set forth by SEQ ID NO: 2 and the structure of a "non-naturally occurring mutant polypeptide" is not disclosed by either the prior art or the instant specification. Thus, it is not clear what the structure of a "non-naturally occurring mutant polypeptide" is. As noted above, the claimed polypeptides are further drawn to specific functional limitations, including being capable of mediating retroviral infection of a mouse or human cell; see at least claim 4.

However, the instant specification does not provide adequate written description for the correlation between the claimed functional limitations and a structure that is a "non-naturally occurring mutant polypeptide".

Separately, note that the instant application fails to support the term "non-naturally occurring mutant polypeptide" as originally filed; Applicant is invited to show otherwise.

In view of the wide scope of the unknown polypeptide structures claimed, including a "non-naturally occurring polypeptide", and the lack of support provided by the instant specification in disclosing any structure to function correlation, the claims are rejected as lacking adequate written description in the instant specification.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 9, 43-48 and 50-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al. (*Nature*, 1981-cited by IDS).

Pedersen et al. disclose the isolation of the SL3-2 virus and characterize the region which encodes the gp70 envelope glycoprotein (see whole document, including abstract). It is noted that this virus is able to mediate infection of mouse cells (see abstract and previous Remarks by Applicant, p. 14); thus, the functional limitations of the claims above are considered inherent features of this protein.

Note that the protein set forth by SEQ ID NO: 2 is the envelope protein of SL3-2 and thus, expressing in combination with sequencing the characterized sequence which encodes for the envelope protein would inherently result in the production of an isolated protein according to SEQ ID NO: 2.

Although Pedersen et al. does not provide the sequence of set forth by SEQ ID NO: 2, it would have been obvious to sequence the envelope glycoprotein described by Pedersen et al. to one of ordinary skill in the art. One would have been motivated to do so in order for further experimentation, such as sequence alignment studies of different envelope protein from different viruses. There would have been a reasonable expectation of success, given protein sequencing is widely known and commonly used (see Table 1, p. 169 of Pedersen disclosing amino acid sequences of other viruses). The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
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